

OCT 10 1996

***Baxter***

K963390

**XII. SMDA REQUIREMENTS (continued)**

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS  
BIOPSY INTRODUCER NEEDLE**

Intended Use:	Biopsy Introducer Needles are devices that are used to guide procedural biopsy needles coaxially to the location of tissue masses or lesions located throughout the body.
Substantial Equivalence:	<p>The Baxter Biopsy Introducer Needle is substantially equivalent to the Bard® TruGuide® Coaxial Needle predicate device in that:</p> <ul style="list-style-type: none"><li>- the intended use is the same</li><li>- the performance attributes are the same</li></ul>
Summary of testing:	The materials used in the fabrication of the Biopsy Introducer Needles were evaluated through appropriate biological qualification safety tests as identified in ISO 10993, Part 1 - "Biological Evaluation of Medical Devices". The biocompatibility tests performed were Cytotoxicity, Sensitization, irritation or intracutaneous reactivity, acute systemic toxicity, Hemolysis, and Pyrogenicity as required. These materials meet the requirements of the tests and are found to be acceptable for the intended use.